UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ILLINOIS

PAUL HILLS,	
Plaintiff, v.))) Case No
BAXTER HEALTHCARE CORP., BAXTER INTERNATIONAL INC. and WYETH SUBSIDIARY ILLINOIS CORPORATION F/K/A SCIENTIFIC PROTEIN LABORATORIES Defendants.) FILED: JUNE 9 , 2008) 08CV3329) JUDGE LEFKOW) MAGISTRATE JUDGE COX) NF)
))

NOTICE OF REMOVAL

Pursuant to 28 U.S.C. §§ 1331, 1441, and 1446, Defendants Baxter Healthcare Corporation ("BHC") and Baxter International Inc. ("BII") file this Notice of Removal to remove this civil action from the Circuit Court of Cook County, State of Illinois, where it was filed as Civil Action No. 2008-L-004473, to the United States District Court for the Northern District of Illinois, and state as follows:

- 1. Defendants are named Defendants in a civil action pending in the Circuit Court of Cook County, State of Illinois, styled as *Paul Hills, Plaintiff v. Baxter Healthcare Corp., Baxter International Inc. and Wyeth Subsidiary Illinois Corporation f/k/a Scientific Protein Laboratories, Defendants* (the "State Court Action").
- 2. Copies of all process, pleadings and orders that had been filed in the State Court Action and served on or by Defendants as of the filing of this Notice of Removal are collectively attached as Exhibit A.

- 3. On or about May 8, 2008, service of process in the State Court Action was effected upon Defendants.
- 4. The action involves allegations related to Defendants' manufacture and supply of heparin. Specifically, Plaintiff asserts claims for strict liability and negligence predicated on allegations that Defendants, *inter alia*: (1) manufactured and supplied and contaminated heparin that was administered to Plaintiff; (2) failed to warn Plaintiff and others of the heparin's condition and (3) failed to recall the heparin soon enough. (*See* Compl. Counts I-II, ¶¶ 48-58, Counts III-IV, ¶¶ 48-60).
- 5. The allegations in the Complaint overlap with similar allegations made in at least twenty other heparin-related lawsuits that have recently been filed throughout the United States. At least five of these other lawsuits are styled as class actions. Plaintiffs' counsel in one putative class action, *D'Amico v. Baxter Healthcare Corp.*, No. 9:08-cv-80311-KAM (S.D. Fla.), has moved the Judicial Panel for Multidistrict Litigation (JPML) to consolidate these cases into a Multidistrict Litigation (MDL). *See* Motion of Plaintiff David D'Amico for Transfer of Actions to Southern District of Florida for Coordinated or Consolidated Pretrial Proceedings Pursuant to 28 U.S.C. Sec. 1407, *In re Heparin Prods. Liab. Litig.*, MDL No. 1953. Defendants and other affected parties have responded in support of consolidation, and the JPML heard argument on the motion at its bimonthly meeting on May 29, 2008. If this case is removed and an MDL is approved, Baxter will move to transfer this case to the MDL for consolidated proceedings.

FEDERAL QUESTION JURISDICTION

6. Plaintiff's Complaint is properly removable to federal court because Plaintiff's claims raise a substantial federal question and therefore provide original federal question jurisdiction over this action under 28 U.S.C. § 1331. *See* 28 U.S.C. § 1441(a); *Grable & Sons Metal Prods., Inc. v. Darue Engr. & Mfg.*, 545 U.S. 308, 125 S. Ct. 2363 (2005) (federal

question jurisdiction proper where a state-law claim necessarily raises a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities).

- 7. Among other things, Plaintiff alleges that Defendants were negligent in that they "knew or should have known that these multiple-dose heparin vials were defective" (see Compl. Counts I-IV ¶ 29) and that Defendants negligently "continued to supply and sell the multiple-dose heparin vials ... without providing any warnings about the risks and drugs associated with the multiple-dose heparin vials" (see Compl. Counts I-IV ¶ 31). Plaintiff further alleges that Defendants' were negligent in the manufacture, inspection, packaging, and marketing of their heparin (see Compl. Counts III-IV ¶ 56) and that the heparin was "contaminated." (See Compl. Counts I-IV ¶ 53).
- 8. Moreover, Plaintiff alleges that Baxter failed to exercise reasonable care in obtaining heparin's active pharmaceutical ingredient (API) from a plant that had not met the requisite requirements for importation and/or sale within the United States, "includ[ing], but...not necessarily limited to, inspection and approval by the Food and Drug Administration...." (Compl. Counts I-IV, ¶ 26) Whether the producers and suppliers at issue were properly FDA-inspected and/or approved requires resolution of federal law.
- 9. Federal laws and regulations are implicated by additional allegations raised by Plaintiff's complaint, including Plaintiff's allegations that BHC and BII breached a duty of care in the "design, manufacture, testing, marketing, distributing, sale, and/or post-sale surveillance of [heparin]" and in failing to warn. (Counts I-IV, ¶¶ 31-32, Counts III ¶ 54). The United States Food and Drug Administration ("FDA") is charged with the oversight of prescription drugs through the complex federal regulatory scheme set forth in the Federal Food, Drug, and

Cosmetics Act, 21 U.S.C. §§ 301 *et seq.* ("FDCA") and its accompanying regulations. Accordingly, the statues, laws, regulations, and safety codes at issue -- pertaining to the methods by which heparin is "manufactured, fabricated, packaged, labeled, marketed, distributed, and/or sold" and so forth -- are federal. This Court necessarily will be called upon to apply these federal statutes and regulations to decide the issues in Plaintiff's complaint.

- 10. The federal requirements at stake in deciding issues raised by Plaintiff's complaint include (but are not limited to) those related to approval and inspection of foreign facilities, importation of components for prescription drugs, manufacturing requirements, adulteration, the new drug approval process, warning and labeling, testing, adverse event report monitoring, and recall.
- 11. Plaintiff's claims for relief are inextricably intertwined with the comprehensive federal scheme governing prescription drugs. In contending that Defendants are liable in this case for heparin allegedly administered to Plaintiff Paul Hills, Plaintiff is challenging the adequacy of FDCA and FDA rules, regulations, and procedures with which Defendants complied.
- 12. Plaintiff's complaint also directly challenges numerous FDA determinations related to Defendants' heparin, including (but not limited to) its determinations related to inspection and approval of facilities, importation, new drug approval, testing, warnings and labeling, and recall. (*See* Compl. Counts I-IV, ¶¶ 25-27, Counts III-IV, ¶ 56).
- 13. For all of these reasons, Plaintiff's well-pleaded complaint necessarily raises federal questions that are actually disputed and substantial. Thus, Plaintiff's complaint raises a substantial federal question.

- 14. A federal forum may entertain this dispute without disturbing any congressionally approved balance of federal and state judicial responsibilities. Indeed, the federal government heavily regulates the drug industry through the FDA and FDCA and has a special interest in cases implicating foreign commerce -- making this case particularly appropriate for federal court jurisdiction.
- 15. Accordingly, removal is proper under federal law since this is a civil action brought in state court over which the federal court has original jurisdiction based on the existence of a substantial federal question. *See* 28 U.S.C. § 1331; *see id.* § 1441.
- 16. Under 28 U.S.C. § 1441, principles of pendant jurisdiction, and supplemental jurisdiction under 28 U.S.C. § 1367, where the Court has jurisdiction over any portion of the action, the entire action may be removed to this Court.

THE OTHER REMOVAL PREREQUISITES HAVE BEEN SATISFIED

- 17. The prerequisites for removal under 28 U.S.C. § 1441 have been met.
- 18. This Notice of Removal is timely filed pursuant to 28 U.S.C. § 1446(b) in that it is being filed within thirty (30) days after the first receipt by Defendants through service of the Complaint. Defendants were served with the Complaint on May 8, 2008. *See* Exhibit A.
- 19. All properly served defendants consent to this removal. Furthermore, although SPL has not yet been served, SPL consents to the removal.
- 20. Pursuant to 28 U.S.C. § 1446(d), copies of this notice are being served on all counsel of record and the clerk of the Circuit Court of Cook County, State of Illinois. *See* Exhibit B.
- 21. Removal to the United States District Court for the Northern District of Illinois is appropriate because this action is being removed from the Circuit Court of Cook County, State of Illinois, which is located within the Northern District of Illinois.

22. By removing this action to this Court, Defendants do not waive any defense

available to them.

23. If any question arises as to the propriety of the removal of this action, Defendants

request the opportunity to present a brief and oral argument in support of its position that this

case is removable.

WHEREFORE, Baxter Healthcare Corporation and Baxter International Inc. respectfully

request that this Notice of Removal be filed; that this action in the Circuit Court of Cook County,

State of Illinois be removed to this Court; and that no further proceedings be had in the case in

the Circuit Court of Cook County, State of Illinois.

Dated this 9th day of June, 2008.

Respectfully submitted,

/s/ Leslie M. Smith, P.C.

Leslie M. Smith, P.C., Attorney No. 6196244

Kirkland & Ellis LLP

200 East Randolph Drive

Chicago, IL 60601

telephone: (312) 861-2000

facsimile: (312) 861-2200

CERTIFICATE OF SERVICE

I, Leslie M. Smith, P.C. do hereby certify that on June 9, 2008, I caused a copy of the foregoing **NOTICE OF REMOVAL** to be served on Plaintiff's counsel by overnight delivery:

Devon C. Bruce POWER, ROGERS & SMITH 70 W. Madison Street, Suite 5500 Chicago, Illinois 60602 Tel: (312) 236-9381

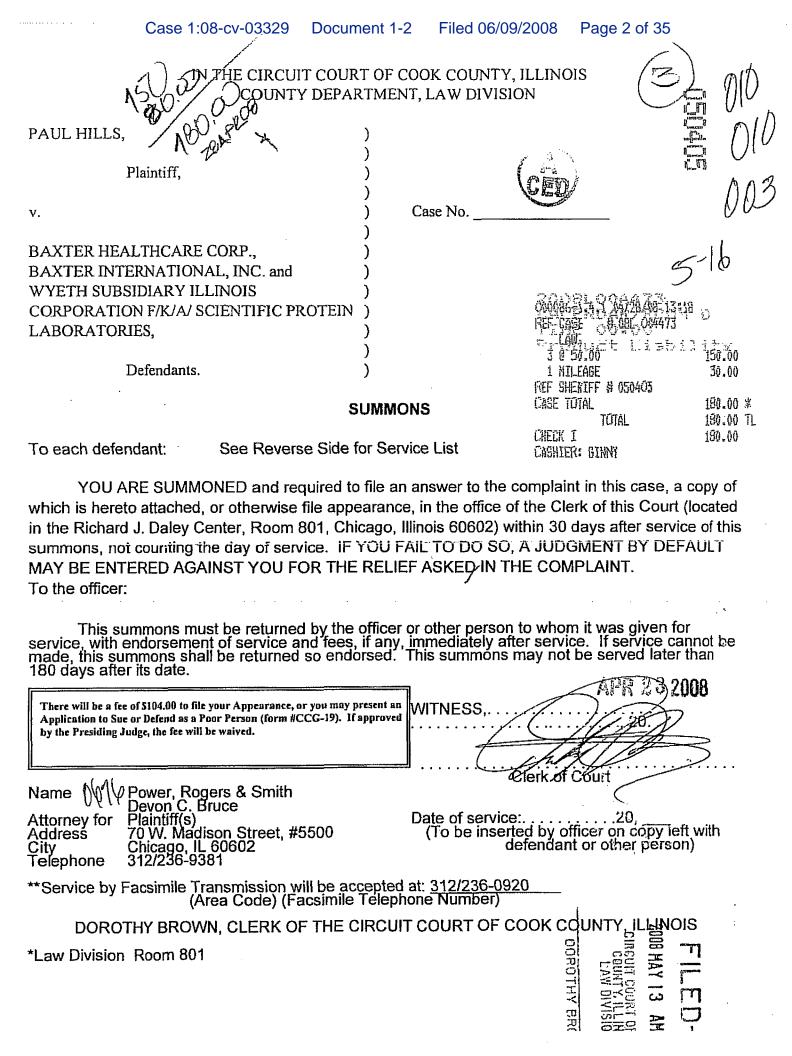
Fax: (312) 236-0920

This	9th	day	of	June,	2008
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/s/ Leslie M. Smith, P.C.
Leslie M. Smith, P.C.

EXHIBIT A

08CV3329 JUDGE LEFKOW MAGISTRATE JUDGE COX NF



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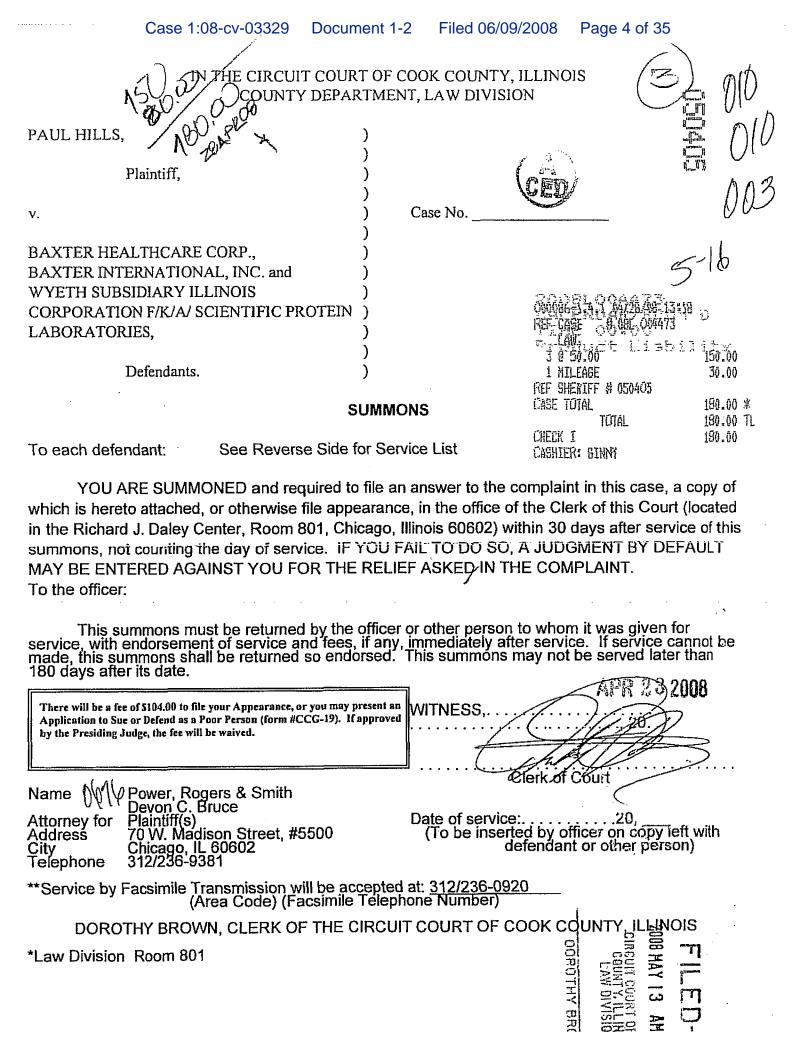
SHERIFF'S OFFICE OF COOK COUNTY, ILLINOIS

STROM 2696-SHERIFF'S NUMBER 050405-001L LASE NUMBER 08L004473 DEPUTY: FILED DT 04-23-2008 RECEIVED DT 04-28-2008 DIE DT 05-16-2008 MULTIPLE SERVICE DEFENDANT ATTORNEY BAXTER HEALTHCARE CORP. POWER ROGERS & SMITH, P.C. 208 S LA SALLE ST 70 W MADISON ST CHICAGO IL. 60604 CHICAGO IL. 60601 **STE 814** 312 236-9381 PLAINTIFF PAUL HILLS SERVICE INFORMATION: DD CT CORP SYSTEMS R/A (A) I CERTIFY THAT I SERVED THIS SUMMONS ON THE DEFENDANT AS FOLLOWS:1 PERSONAL SERVICE: BY LEAVING A COPY OF THE SUMMONS AND COMPLAINT WITH THE NAMED DEFENDANT PERSONALLY. ...2 SUBSTITUTE SERVICE: BY LEAVING A COPY OF THE SUMMONS AND A COPY OF THE COMPLAINT AT THE DEFENDANT'S USUAL PLACE. OF ABODE WITH SOME PERSON OF THE FAMILY OR A PERSON RESIDING THERE, OF THE AGE OF 13 YEARS OR UPWARDS, AND INFORMING THAT PERSON OF THE CONTENTS THEREOF. ALSO, A COPY OF THE SUMMONS WAS MAILED ON THE 20 , IN A SEALED ENVELOPE WITH POSTAGE FULLY DAY OF PREPAID, ADDRESSED TO THE DEFENDANT AT HIS OR HER USUAL PLACE OF ABODE. SAID PARTY REFUSED NAME SERVICE ON: CORPORATION COMPANY BUSINESS PARTNERSHIP BY LEAVING A COPY OF THE SUMMONS AND COMPLAINT (OR INTERROGATORIES) WITH THE REGISTERED AGENT, AUTHORIZED PERSON OR PARTNER OF THE DEFENDANT.4 CERTIFIED MAIL (B) THOMAS J. DART, SHERIFF, BY: RACE (1) AGE(Q1 NAME OF DEFENDANT BAXTER HEALTHCARE CORP. D. SCHULZ A.P. WRIT SERVED ON ADDITIONAL REMARKS THE NAMED DEFENDANT WAS NOT SERVED. ATTEMPTED SERVICES TYPE OF BLDG DATE TIME A.M./P.M. NEIGHBORS NAME ADDRESS **REASON NOT SERVED: 07 EMPLOYER REFUSAL** 01 MOVED 08 RETURNED BY ATTY 09 DECEASED 02 NO CONTACT 03 EMPTY LOT 10 BLDG DEMOLISHED 11 NO REGISTERED AGT. 04 NOT LISTED 12 OTHER REASONS 05 WRONG ADDRESS 06 NO SUCH ADDRESS 13 OUT OF COUNTY

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(B) THOMAS J. DART, SHERIFF, BY: 1 SEX M/F RACE AGE CO 2 NAME OF DEFENDANT BAXTER INTERNATIONAL WRIT SERVED ON D. SCHULZ A.P. THIS DAY OF MAY 20 8 TIME	INC. EMP.H.
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IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS COUNTY DEPARTMENT, LAW DIVISION

PAUL HILLS,				
Plaintiff,				
v.)	Case No		**. 3	
)		THE HOLD GROWN	••	į
BAXTER HEALTHCARE CORP.,)				•
BAXTER INTERNATIONAL, INC. and)			:	
WYETH SUBSIDIARY ILLINOIS)		Kong Hastinger (M. 1997) (Albert C.		
CORPORATION F/K/A/ SCIENTIFIC PROTEIN.)				
LABORATORIES,)				`* <u>;</u>
Defendants.			500	

COMPLAINT AT LAW

Now comes Paul Hills, by and through his counsel, POWER, ROGERS & SMITH, and hereby states hypothetically and in the alternative as follows:

COUNT I Baxter Healthcare & Baxter International, Inc. (Wrongful Death- Strict Liability)

The Parties

- 1. Plaintiff, Paul Hills, was at all relevant times was a resident of Evanston, Illinois, Cook County.
- 2. Defendant, Baxter Healthcare Corporation has its principle place of business at One Baxter Parkway in Deerfield, Illinois.
- 3. Defendant, Baxter International Inc. has its principle place of business at One Baxter Parkway in Deerfield, Illinois.
- 4. At all relevant times, the registered agent for Baxter Healthcare Corporation was CT Corporation located in Cook County, Illinois.
- 5. At all relevant times, the registered agent for Baxter International was CT Corporation located in Cook County, Illinois.
- 6. Scientific Protein Laboratories is a corporation which produces ingredients for intravenous heparin. Scientific Protein Laboratories has its principle place of business in

Waunakee, Wisconsin.

Case 1:08-cv-03329

- 7. At all relevant times, Baxter Healthcare Corporation was in the business of designing, manufacturing and distributing intravenous Heparin for profit.
- 8. At all relevant times, Baxter Healthcare Corporation marketed and advertised is pharmaceutical sales within Cook County.
- 9. At all relevant times, Baxter Healthcare Corporation employed a number of employees that worked within Cook County, Illinois.
- 10. At all relevant times, Baxter Healthcare Corporation sold millions of dollars worth of pharmaceutical products including intravenous Heparin to healthcare providers in Cook County, Illinois.

Contaminated Heparin

- 11. Heparin is a prescription drug in a class of medications called anti-coagulants also known as blood thinners.
- 12. Heparin is a pork-derived product and one of the oldest drugs currently still in widespread clinical use, having been used since the early 1990s.
- 13. Heparin works by decreasing the clotting ability of the blood, thereby preventing the actual formation of clots or preventing the extension of existing clots within the blood.
- 14. It is most often administered intravenously and is used primarily to decrease the chance of clots forming in patients undergoing certain medical procedures such as cardiac surgery, in preventing the formation of clots in catheters (small plastic tubes through which medication is administered or blood drawn) such as in kidney dialysis, and for other such conditions like pulmonary emboli.
- 15. The Food and Drug Administration ("FDA") estimates that more than 1 million multiple-dose vials are sold each month in the United States.
- 16. Baxter is one of the largest producers of Heparin in the United States, and its sales of heparin constitute at least a 50% market share.
- 17. Baxter sells an estimated 35 million units of Heparin per year, with annual sales of approximately \$30 million dollars.
- 18. Baxter reported total sales in the amount of \$11.3 billion dollars for 2007, with over 70% of its revenues being sourced form products in market-leading positions.
- 19. The multiple-dose heparin vials were represented by Defendants to be safe and effective

for their intended uses, including, but not limited to, intravenous administration during hemodialysis.

- 20. The multiple-dose heparin vials were defective in their manufacture.
- 21. Defendants are designers, developers, manufacturers, wholesales, retailers, fabricators, suppliers and/or distributors of the multiple-dose heparin vials, one or more of which was administered to the Paul Hills during a hemodialysis session or sessions.
- 22. The multiple-dose heparin vials were manufactured, fabricated, distributed, supplied and/or placed in the stream of interstate commerce by Defendants.
- 23. Defendants obtained the component parts for the multiple-dose heparin vials from unidentified supply companies, including, but not limited to, Scientific Protein Laboratories, which has two plants which supply the active pharmaceutical ingredient for heparin to Defendants.
- 24. The active pharmaceutical ingredient in heparin is an enzyme that is extracted from pig intestines.
- 25. One of these plants is located in China and upon information belief, has not met the requisite requirements for importation and/or sale within the United States.
- 26. Such requirements include, but are not necessarily limited to, inspection and approval by the Food and Drug Administration as is required for any facility to supply drug ingredients to the United States.
- 27. Upon information and belief, Defendants knew or should have known of such non-compliance or lack of plant inspection and/or approval, which is required for all foreign facilities.
- 28. Such multiple-dose heparin vials were defective at the time they were placed in the stream of commerce.
- 29. Baxter knew or should have known that these multiple-dose heparin vials were defective at the time they left Baxter's control and custody.
- 30. Defendants also knew or should have known that the multiple-dose heparin vials were causing adverse reactions for patients, such as Paul Hills.
- 31. Nothwithstanding their knowledge, Baxter continued to supply and sell the multiple-dose heparin vials up to and until just recently, without providing any warnings about the risks and drugs associated with the multiple-dose heparin vials to members of the public and the medical community, including Paul Hills.

- 32. At all material times, Baxter intentionally concealed from the public and members of the medical community, including Paul Hills, the risks and dangers associated with the use of the multiple-dose heparin vials, and/or has misrepresented the safety, quality and performance of multiple-dose heparin vials.
- 33. On or about January 17, 2008, Baxter and the FDA both issued press releases regarding the voluntary recall by Baxter of nine lots of Heparin Sodium Injection multiple dose vials in 1000 units/mL concentrations of 10mL and 30mL vials, 5000 units/mL concentration of 10mL vials and 10,000 units for 4mL vials.
- 34. This voluntary recall was the result of an abnormal increase in the reports of adverse patient reactions associated with the use of heparin.
- 35. These adverse patient reactions included the following: allergic or hypersensitivity-type reactions, with symptoms of oral swelling, abdominal pains, burning sensation, chest pain, diarrhea, dizziness, drug ineffectiveness, dyspepsia, dyspnea, erythema, flushing, headache, hyperhidrosis, hypoesthesia, increased lacrimation, loss of consciousness, malaise, nausea, pallor, palpitations, paresthesia, pharyngeal edema, restlessness, vomiting/retching, shortness of breath, stomach discomfort, sweating, tachycardia, thirst, trismus, and unresponsiveness to stimul, as well as cases of severe hypotension requiring treatment.
- 36. These adverse reports began as early as November 19, 2007, from more than nineteen dialysis facilities in more than twelve states.
- 37. An estimated 40% of the adverse reports have been categorized as serious by the FDA and there have been at least four reported deaths.
- 38. The bulk of the adverse reports have centered on adverse events occurring at hemodialysis centers.
- 39. According to the FDA, there has been a significant increase in reported adverse events associated with the use of Heparin, with an estimated 350 events reported since December 2007 in contrast to less then 100 reports in 2007.
- 40. Based upon the clusters of adverse reports, Baxter and the Center for Disease Control ("CDC") initially identified nine specific Heparin manufacturing lots with a suggested link to those cases.
- 41. The initial nine lots recalled by Baxter ware for the following Heparin products: NDC#00641-2440-45, NDC#00641-2440-41, NDC#00641-2450-45, and NDC#00641-2450-41. The products include the following lots:
- a. Heparin 1000 units/mL, 10mL vial, expiration date 10/2009, Lot #107054
- b. Heparin 1000 units/mL, 10 mL vial, expiration date 11/2009, Lot #117085
- c. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2008, Lot #047056

- d. Heparin 1000 units/mL, 30 mL vial, expiration date 9/2009, Lot #097081
- e. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2009, Lot #107024
- f. Heparin 1000 units/mL, 30mL vial, expiration date 10/2009, Lot #107064
- g. Heparin 1000 units/mL, 30mL, expiration date 10/2009, Lot #107066
- h. Heparin 1000 units/mL, 30 mL, expiration date 10/2009, Lot #107074
- i. Heparin 1000 units/mL, 30 mL, expiration date 10/2009, Lot #107111
- 42. Upon information and belief, these nine lots were all manufactured at a single facility between September and November of 207.
- 43. Upon information and belief, the active pharmaceutical ingredient in these products was at least in part provided by a third party supplier from an unapproved facility in China.
- 44. However, according to FDA updates, more recent information indicates that comparable adverse events are continuing to be reported that are associated with the use of multiple-dose heparin vials of different manufacturing lots than those identified in the initial voluntary recall.
- 45. The FDA began inspections of Baxter's manufacturing plant in Cherry Hill, New Jersey and its processes on or about January 16, 2008.
- 46. The FDA and CDC are continuing with an investigation to discover the underlying cause of these anomalous adverse events.
- 47. As of February 11, 2008, Baxter ceased production of all of its multiple-dose vials of injectible heparin due to the potentially life threatening adverse and allergic reactions and incidents of hypotension that are being reported.

Paul Hills

- 48. On or about July 24, 2007, Paul Hills had a surgical procedure performed for an abodminal aortic aneurysm at Evanston Hospital in Evanston, IL.
- 49. On or about July 24, 2007, the aforesaid procedure performed on Paul Hills was successful and he was expected at that point in time to have a complete and full recovery.
- 50. On or about July 24, 2007, Paul Hills was administered the aforesaid contaminated Heparin manufactured by Baxter.
- 51. Following the July 24, 2007 procedure, Paul Hills manifested signs and symptoms consistent with the administration of contaminated heparin including: dizziness, fainting, stomach pain and a fast heart rate.
- 52. On and after July 24, 2007, Paul Hills had an extensive hospitalization due to complications from the contaminated heparin.

- On and prior to July 24, 2007, Baxter Healthcare manufactured and distributed the 53. aforesaid contaminated Heparin product which was unreasonably dangerous for its intended use and was defective.
- 54. Prior to July 24, 2007, the aforesaid contaminated Heparin was introduced into the stream of commerce by Baxter Healthcare and/or Baxter International.
- 55. Prior to July 24, 2007, and at the time Baxter Healthcare and/or Baxter International introduced the aforementioned contaminated heparin into the stream of commerce the heparin contained a material defect.
- 56. On July 24, 2007 and at the time the contaminated heparin was administered to Paul Hills, the heparin failed to perform in the manner reasonably to be expected.
- Prior to July 24, 2007, Baxter Healthcare and/or Baxter International failed to adequately warn of the danger of the contamination in the aforementioned contaminated heparin.
- As a direct and proximate result of Defendants' defective multiple-dose heparin vials, Paul Hills has been injured and incurred substantial damages, including, but not limited to. medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, and other damages for which Defendants are liable.

WHEREFORE, plaintiff, PAUL HILLS, by his attorneys, POWER ROGERS & SMITH, demands judgment against Defendant, BAXTER HEALTHCARE and/or BAXTER INTERNATIONAL INC., in such sum of money in excess of FIFTY THOUSAND DOLLARS (\$50,000.00) as shall represent fair and just compensation.

Scientific Protein Laboratories (Wrongful Death-Strict Liability)

- 1. Plaintiff, Paul Hills, was at all relevant times was a resident of Evanston, Illinois, Cook County.
- 2. Defendant, Baxter Healthcare Corporation has its principle place of business at One Baxter Parkway in Deerfield, Illinois.
- 3. Defendant, Baxter International Inc. has its principle place of business at One Baxter Parkway in Deerfield, Illinois.
- 4. At all relevant times, the registered agent for Baxter Healthcare Corporation was CT Corporation located in Cook County, Illinois.
- 5. At all relevant times, the registered agent for Baxter International was CT Corporation located in Cook County, Illinois.
- 6. Scientific Protein Laboratories is a corporation which produces ingredients for intravenous heparin. Scientific Protein Laboratories has its principle place of business in Waunakee, Wisconsin.
- 7. At all relevant times, Baxter Healthcare Corporation was in the business of designing, manufacturing and distributing intravenous Heparin for profit.
- 8. At all relevant times, Baxter Healthcare Corporation marketed and advertised is pharmaceutical sales within Cook County.
- 9. At all relevant times, Baxter Healthcare Corporation employed a number of employees that worked within Cook County, Illinois.
- 10. At all relevant times, Baxter Healthcare Corporation sold millions of dollars worth of pharmaceutical products including intravenous Heparin to healthcare providers in Cook County, Illinois.

Contaminated Heparin

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- 12. Heparin is a pork-derived product and one of the oldest drugs currently still in widespread clinical use, having been used since the early 1990s.
- 13. Heparin works by decreasing the clotting ability of the blood, thereby preventing the

actual formation of clots or preventing the extension of existing clots within the blood.

- 14. It is most often administered intravenously and is used primarily to decrease the chance of clots forming in patients undergoing certain medical procedures such as cardiac surgery, in preventing the formation of clots in catheters (small plastic tubes through which medication is administered or blood drawn) such as in kidney dialysis, and for other such conditions like pulmonary emboli.
- 15. The Food and Drug Administration ("FDA") estimates that more than 1 million multiple-dose vials are sold each month in the United States.
- 16. Baxter is one of the largest producers of Heparin in the United States, and its sales of heparin constitute at least a 50% market share.
- 17. Baxter sells an estimated 35 million units of Heparin per year, with annual sales of approximately \$30 million dollars.
- 18. Baxter reported total sales in the amount of \$11.3 billion dollars for 2007, with over 70% of its revenues being sourced form products in market-leading positions.
- 19. The multiple-dose heparin vials were represented by Defendants to be safe and effective for their intended uses, including, but not limited to, intravenous administration during hemodialysis.
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- 24. The active pharmaceutical ingredient in heparin is an enzyme that is extracted from pig intestines.
- 25. One of these plants is located in China and upon information belief, has not met the requisite requirements for importation and/or sale within the United States.
- 26. Such requirements include, but are not necessarily limited to, inspection and approval by the Food and Drug Administration as is required for any facility to supple drug ingredients to the

United States.

- 27. Upon information and belief, Defendants knew or should have known of such non-compliance or lack of plant inspection and/or approval, which is required for all foreign facilities.
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- 29. Baxter knew or should have known that these multiple-dose heparin vials were defective at the time they left Baxter's control and custody.
- 30. Defendants also knew or should have known that the multiple-dose heparin vials were causing adverse reactions for patients, such as Paul Hills.
- 31. Nothwithstanding their knowledge, Baxter continued to supply and sell the multiple-dose heparin vials up to and until just recently, without providing any warnings about the risks and drugs associated with the multiple-dose heparin vials to members of the public and the medical community, including Paul Hills.
- 32. At all material times, Baxter intentionally concealed from the public and members of the medical community, including Paul Hills, the risks and dangers associated with the use of the multiple-dose heparin vials, and/or has misrepresented the safety, quality and performance of multiple-dose heparin vials.
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- 35. These adverse patient reactions included the following: allergic or hypersensitivity-type reactions, with symptoms of oral swelling, abdominal pains, burning sensation, chest pain, diarrhea, dizziness, drug ineffectiveness, dyspepsia, dyspnea, erythema, flushing, headache, hyperhidrosis, hypoesthesia, increased lacrimation, loss of consciousness, malaise, nausea, pallor, palpitations, paresthesia, pharyngeal edema, restlessness, vomiting/retching, shortness of breath, stomach discomfort, sweating, tachycardia, thirst, trismus, and unresponsiveness to stimul, as well as cases of severe hypotension requiring treatment.
- 36. These adverse reports began as early as November 19, 2007, from more than nineteen dialysis facilities in more than twelve states.
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and there have been at least four reported deaths.

- 38. The bulk of the adverse reports have centered on adverse events occurring at hemodialysis centers.
- 39. According to the FDA, there has been a significant increase in reported adverse events associated with the use of Heparin, with an estimated 350 events reported since December 2007 in contrast to less then 100 reports in 2007.
- 40. Based upon the clusters of adverse reports, Baxter and the Center for Disease Control ("CDC") initially identified nine specific Heparin manufacturing lots with a suggested link to those cases.
- 41. The initial nine lots recalled by Baxter ware for the following Heparin products: NDC#00641-2440-45, NDC#00641-2440-41, NDC#00641-2450-45, and NDC#00641-2450-41. The products include the following lots:
- a. Heparin 1000 units/mL, 10mL vial, expiration date 10/2009, Lot #107054
- b. Heparin 1000 units/mL, 10 mL vial, expiration date 11/2009, Lot #117085
- c. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2008, Lot #047056
- d. Heparin 1000 units/mL, 30 mL vial, expiration date 9/2009, Lot #097081
- e. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2009, Lot #107024
- f. Heparin 1000 units/mL, 30mL vial, expiration date 10/2009, Lot #107064
- g. Heparin 1000 units/mL, 30mL, expiration date 10/2009, Lot #107066
- h. Heparin 1000 units/mL, 30 mL, expiration date 10/2009, Lot #107074
- i. Heparin 1000 units/mL, 30 mL, expiration date 10/2009, Lot #107111
- 42. Upon information and belief, these nine lots were all manufactured at a single facility between September and November of 207.
- 43. Upon information and belief, the active pharmaceutical ingredient in these products was at least in part provided by a third party supplier from an unapproved facility in China.
- 44. However, according to FDA updates, more recent information indicates that comparable adverse events are continuing to be reported that are associated with the use of multiple-dose heparin vials of different manufacturing lots than those identified in the initial voluntary recall.
- 45. The FDA began inspections of Baxter's manufacturing plant in Cherry Hill, New Jersey and its processes on or about January 16, 2008.
- 46. The FDA and CDC are continuing with an investigation to discover the underlying cause of these anomalous adverse events.
- 47. As of February 11, 2008, Baxter ceased production of all of its multiple-dose vials of injectible heparin due to the potentially life threatening adverse and allergic reactions and

incidents of hypotension that are being reported.

Paul Hills

- 48. On or about July 24, 2007, Paul Hills had a surgical procedure performed for an abdominal aneurysm at Evanston Hospital in Evanston, IL.
- 49. On or about July 24, 2007, the aforesaid procedure performed on Paul Hills was successful and he was expected at that point in time to have a complete and full recovery.
- 50. On or about July 24, 2007, Paul Hills was administered the aforesaid contaminated Heparin manufactured by Baxter.
- 51. Following the July 24, 2007 procedure, Paul Hills manifested signs and symptoms consistent with the administration of contaminated heparin including: dizziness, fainting, stomach pain and a fast heart rate.
- 52. On and after July 24, 2007, Paul Hills had an extensive hospitalization due to complications from the contaminated heparin.
- 53. On and prior to July 24, 2007, Baxter Healthcare manufactured and distributed the aforesaid contaminated Heparin product which was unreasonably dangerous for its intended use and was defective.
- 54. Prior to July 24, 2007, the aforesaid contaminated Heparin was introduced into the stream of commerce by Baxter Healthcare and/or Baxter International.
- 55. Prior to July 24, 2007, and at the time Baxter Healthcare and/or Baxter International introduced the aforementioned contaminated heparin into the stream of commerce the heparin contained a material defect.
- 56. On July 24, 2007 and at the time the contaminated heparin was administered to Paul Hills, the heparin failed to perform in the manner reasonably to be expected.
- 57. Prior to July 24, 2007, Baxter Healthcare and/or Baxter International failed to adequately warn of the danger of the contamination in the aforementioned contaminated heparin.
- As a direct and proximate result of Defendants' defective multiple-dose heparin vials, Paul Hills has been injured and incurred substantial damages, including, but not limited to, medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, and other damages for which Defendants are liable.

WHEREFORE, plaintiff, PAUL HILLS, by his attorneys, POWER ROGERS & SMITH, demands judgment against Defendant, PROTEIN SCIENTIFIC LABORATORIES, in such sum of money in excess of FIFTY THOUSAND DOLLARS (\$50,000.00) as shall represent fair and

just compensation.

Count III Baxter Healthcare and Baxter International Inc. (Wrongful Death- Negligence)

- 1. Plaintiff, Paul Hills, was at all relevant times was a resident of Evanston, Illinois, Cook County.
- 2. Defendant, Baxter Healthcare Corporation has its principle place of business at One Baxter Parkway in Deerfield, Illinois.
- 3. Defendant, Baxter International Inc. has its principle place of business at One Baxter Parkway in Deerfield, Illinois.
- 4. At all relevant times, the registered agent for Baxter Healthcare Corporation was CT Corporation located in Cook County, Illinois.
- 5. At all relevant times, the registered agent for Baxter International was CT Corporation located in Cook County, Illinois.
- 6. Scientific Protein Laboratories is a corporation which produces ingredients for intravenous heparin. Scientific Protein Laboratories has its principle place of business in Waunakee, Wisconsin.
- 7. At all relevant times, Baxter Healthcare Corporation was in the business of designing, manufacturing and distributing intravenous Heparin for profit.
- 8. At all relevant times, Baxter Healthcare Corporation marketed and advertised is pharmaceutical sales within Cook County.
- 9. At all relevant times, Baxter Healthcare Corporation employed a number of employees that worked within Cook County, Illinois.
- 10. At all relevant times, Baxter Healthcare Corporation sold millions of dollars worth of pharmaceutical products including intravenous Heparin to healthcare providers in Cook County, Illinois.

Contaminated Heparin

- 11. Heparin is a prescription drug in a class of medications called anti-coagulants also known as blood thinners.
- 12. Heparin is a pork-derived product and one of the oldest drugs currently still in widespread clinical use, having been used since the early 1990s.
- 13. Heparin works by decreasing the clotting ability of the blood, thereby preventing the

actual formation of clots or preventing the extension of existing clots within the blood.

- 14. It is most often administered intravenously and is used primarily to decrease the chance of clots forming in patients undergoing certain medical procedures such as cardiac surgery, in preventing the formation of clots in catheters (small plastic tubes through which medication is administered or blood drawn) such as in kidney dialysis, and for other such conditions like pulmonary emboli.
- 15. The Food and Drug Administration ("FDA") estimates that more than 1 million multiple-dose vials are sold each month in the United States.
- 16. Baxter is one of the largest producers of Heparin in the United States, and its sales of heparin constitute at least a 50% market share.
- 17. Baxter sells an estimated 35 million units of Heparin per year, with annual sales of approximately \$30 million dollars.
- 18. Baxter reported total sales in the amount of \$11.3 billion dollars for 2007, with over 70% of its revenues being sourced form products in market-leading positions.
- 19. The multiple-dose heparin vials were represented by Defendants to be safe and effective for their intended uses, including, but not limited to, intravenous administration during hemodialysis.
- 20. The multiple-dose heparin vials were defective in their manufacture.
- 21. Defendants are designers, developers, manufacturers, wholesales, retailers, fabricators, suppliers and/or distributors of the multiple-dose heparin vials, one or more of which was administered to the Paul Hills during a hemodialysis session or sessions.
- 22. The multiple-dose heparin vials were manufactured, fabricated, distributed, supplied and/or placed in the stream of interstate commerce by Defendants.
- 23. Defendants obtained the component parts for the multiple-dose heparin vials from unidentified supply companies, including, but not limited to, Scientific Protein Laboratories, who has two plants which supply the active pharmaceutical ingredient for heparin to Defendants.
- 24. The active pharmaceutical ingredient in heparin is an enzyme that is extracted from pig intestines.
- 25. One of these plants is located in China and upon information belief, has not met the requisite requirements for importation and/or sale within the United States.
- 26. Such requirements include, but are not necessarily limited to, inspection and approval by the Food and Drug Administration as is required for any facility to supple drug ingredients to the

United States.

- 27. Upon information and belief, Defendants knew or should have known of such non-compliance or lack of plant inspection and/or approval, which is required for all foreign facilities.
- 28. Such multiple-dose heparin vials were defective at the time they were placed in the stream of commerce.
- 29. Baxter knew or should have known that these multiple-dose heparin vials were defective at the time they left Baxter's control and custody.
- 30. Defendants also knew or should have known that the multiple-dose heparin vials were causing adverse reactions for patients, such as Paul Hills.
- 31. Nothwithstanding their knowledge, Baxter continued to supply and sell the multiple-dose heparin vials up to and until just recently, without providing any warnings about the risks and drugs associated with the multiple-dose heparin vials to members of the public and the medical community, including Paul Hills.
- 32. At all material times, Baxter intentionally concealed from the public and members of the medical community, including Paul Hills, the risks and dangers associated with the use of the multiple-dose heparin vials, and/or has misrepresented the safety, quality and performance of multiple-dose heparin vials.
- 33. On or about January 17, 2008, Baxter and the FDA both issued press releases regarding the voluntary recall by Baxter of nine lots of Heparin Sodium Injection multiple dose vials in 1000 units/mL concentrations of 10mL and 30mL vials, 5000 units/mL concentration of 10mL vials and 10,000 units for 4mL vials.
- 34. This voluntary recall was the result of an abnormal increase in the reports of adverse patient reactions associated with the use of heparin.
- 35. These adverse patient reactions included the following: allergic or hypersensitivity-type reactions, with symptoms of oral swelling, abdominal pains, burning sensation, chest pain, diarrhea, dizziness, drug ineffectiveness, dyspepsia, dyspnea, erythema, flushing, headache, hyperhidrosis, hypoesthesia, increased lacrimation, loss of consciousness, malaise, nausea, pallor, palpitations, paresthesia, pharyngeal edema, restlessness, vomiting/retching, shortness of breath, stomach discomfort, sweating, tachycardia, thirst, trismus, and unresponsiveness to stimul, as well as cases of severe hypotension requiring treatment.
- 36. These adverse reports began as early as November 19, 2007, from more than nineteen dialysis facilities in more than twelve states.
- 37. An estimated 40% of the adverse reports have been categorized as serious by the FDA

and there have been at least four reported deaths.

- 38. The bulk of the adverse reports have centered on adverse events occurring at hemodialysis centers.
- 39. According to the FDA, there has been a significant increase in reported adverse events associated with the use of Heparin, with an estimated 350 events reported since December 2007 in contrast to less then 100 reports in 2007.
- 40. Based upon the clusters of adverse reports, Baxter and the Center for Disease Control ("CDC") initially identified nine specific Heparin manufacturing lots with a suggested link to those cases.
- 41. The initial nine lots recalled by Baxter ware for the following Heparin products: NDC#00641-2440-45, NDC#00641-2440-41, NDC#00641-2450-45, and NDC#00641-2450-41. The products include the following lots:
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- c. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2008, Lot #047056
- d. Heparin 1000 units/mL, 30 mL vial, expiration date 9/2009, Lot #097081
- e. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2009, Lot #107024
- f. Heparin 1000 units/mL, 30mL vial, expiration date 10/2009, Lot #107064
- g. Heparin 1000 units/mL, 30mL, expiration date 10/2009, Lot #107066
- h. Heparin 1000 units/mL, 30 mL, expiration date 10/2009, Lot #107074
- i. Heparin 1000 units/mL, 30 mL, expiration date 10/2009, Lot #107111
- 42. Upon information and belief, these nine lots were all manufactured at a single facility between September and November of 207.
- 43. Upon information and belief, the active pharmaceutical ingredient in these products was at least in part provided by a third party supplier from an unapproved facility in China.
- 44. However, according to FDA updates, more recent information indicates that comparable adverse events are continuing to be reported that are associated with the use of multiple-dose heparin vials of different manufacturing lots than those identified in the initial voluntary recall.
- 45. The FDA began inspections of Baxter's manufacturing plant in Cherry Hill, New Jersey and its processes on or about January 16, 2008.
- 46. The FDA and CDC are continuing with an investigation to discover the underlying cause of these anomalous adverse events.
- 47. As of February 11, 2008, Baxter ceased production of all of its multiple-dose vials of injectible heparin due to the potentially life threatening adverse and allergic reactions and

incidents of hypotension that are being reported.

Paul Hills

- 48. On or about July 24, 2007, Paul Hills had a surgical procedure performed for an abdominal aortic aneurysm at Evanston Hospital in Evanston, IL.
- 49. On or about July 24, 2007, the aforesaid procedure performed on Paul Hills was successful and he was expected at that point in time to have a complete and full recovery.
- 50. On or about July 24, 2007, Paul Hills was administered the aforesaid contaminated Heparin manufactured by Baxter.
- 51. Following the July 24, 2007 procedure, Paul Hills manifested signs and symptoms consistent with the administration of contaminated heparin including: dizziness, fainting, stomach pain and a fast heart rate.
- 52. On and after July 24, 2007, Paul Hills had an extensive hospitalization due to complications from the contaminated heparin.
- 53. On and prior to July 24, 2007, Baxter Healthcare manufactured and distributed the aforesaid contaminated Heparin product which was unreasonably dangerous for its intended use and was defective.
- 54. Baxter owed a duty to exercise reasonable care in the design, manufacture, testing, marketing, distributing, sale, and/or post-sale surveillance of these products, including the dose given to Paul Hills, so that it could be safely used for the purpose for which it was intended, or in a reasonable foreseeable manner.
- 55. This duty included the duty not to introduce a dangerous and unfit pharmaceutical drug, such as the multiple-dose heparin vials, into the stream of commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side effects, up to and including death.
- 56. In breach of their duty of care, Baxter was negligent in the manufacturer, testing, distribution, marketing, sale, and/or post-sale surveillance of the multiple-dose heparin vials, including as follows:
- a. Baxter failed to exercise reasonable care in the manufacture of their multiple-dose heparin vials;
- b. Baxter failed to exercise reasonable care in the inspection of their multiple-dose heparin vials;
- c. Baxter failed to exercise reasonable care in the packaging of their multiple-dose heparin vials;

- d. Baxter failed to provide any and adequate warnings about the risks and dangers associated with the use of their multiple-dose heparin vials, as alleged herein;
- e. Baxter failed to completely, accurately and in a timely fashion, disclose the adverse events reports associated with the use of its multiple-dose heparin vials;
- f. Baxter failed to recall, withdraw, and remove their multiple-dose heparin vials from the market once they knew or should have known of the risks and dangers associated with the use thereof;
- g. Baxter failed to promptly respond to data, reports, and publications describing problems associated with their multiple-dose heparin vials by conducting adequate analysis, testing, and surveillance;
- h. Baxter failed to implement pre-marketing and post-marketing measures to notify and warn Paul Hills, as well as his physicians, medical providers, and other members of the medical community, of the risks and dangers associated with the use of the said multiple-dose heparin vials, and to recall the defective multiple-dose heparin vials;
- i. Baxter failed to adequately and reasonably establish, maintain and comport with acceptable quality control mechanisms to prevent defective products from entering the marketplace or from using unsafe ingredients;
- j. Baxter failed to adequately and reasonably ensure quality controls were in the place and as such controls were adhered to obtaining the component parts for the multiple-dose heparin vials, including, but not limited to, the active pharmaceutical ingredient;
- k. Baxter failed to adequately and reasonably ensure compliance with all applicable laws, regulations, and administrative approval or licensing requirements;
- I. Baxter failed to adequately monitor and/or take reasonable precautions to ensure that the active pharmaceutical ingredients in heparin were of suitable quality and safety; and
 - m. Baxter was otherwise negligent and careless.
- 57. Baxter knew or should have known that patients/consumers such as Paul Hills Sean Valenzo would foreseeably suffer injury as a result of their failure to exercise ordinary care as described above.
- 58. Baxter's multiple-dose heparin vials were expected to and did reach Paul Hills without substantial change in the condition as designed, manufactured, marketed, distributed, and sold, prior to their administration to Paul Hills, who used the heparin as intended, or in a reasonably foreseeable manner.

- 59. Baxter's negligent conduct caused substantial harm to Paul Hills.
- 60. As a direct and proximate result of Defendants' defective multiple-dose heparin vials, Paul Hills has been injured and incurred substantial damages, including, but not limited to medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, and other damages for which Defendants are liable.

WHEREFORE, plaintiff, PAUL HILLS, by his attorneys, POWER ROGERS & SMITH, demands judgment against Defendant, BAXTER HEALTHCARE and/or BAXTER INTERNATIONAL INC., in such sum of money in excess of FIFTY THOUSAND DOLLARS (\$50,000.00) as shall represent fair and just compensation.

Count IV Scientific Protein Laboratories (Wrongful Death-Negligence)

- 1. Plaintiff, Paul Hills, was at all relevant times was a resident of Evanston, Illinois, Cook County.
- 2. Defendant, Baxter Healthcare Corporation has its principle place of business at One Baxter Parkway in Deerfield, Illinois.
- 3. Defendant, Baxter International Inc. has its principle place of business at One Baxter Parkway in Deerfield, Illinois.
- 4. At all relevant times, the registered agent for Baxter Healthcare Corporation was CT Corporation located in Cook County, Illinois.
- 5. At all relevant times, the registered agent for Baxter International was CT Corporation located in Cook County, Illinois.
- 6. Scientific Protein Laboratories is a corporation which produces ingredients for intravenous heparin. Scientific Protein Laboratories has its principle place of business in Waunakee, Wisconsin.
- 7. At all relevant times, Baxter Healthcare Corporation was in the business of designing, manufacturing and distributing intravenous Heparin for profit.
- 8. At all relevant times, Baxter Healthcare Corporation marketed and advertised is pharmaceutical sales within Cook County.
- 9. At all relevant times, Baxter Healthcare Corporation employed a number of employees that worked within Cook County, Illinois.
- 10. At all relevant times, Baxter Healthcare Corporation sold millions of dollars worth of pharmaceutical products including intravenous Heparin to healthcare providers in Cook County, Illinois.

Contaminated Heparin

- 11. Heparin is a prescription drug in a class of medications called anti-coagulants also known as blood thinners.
- 12. Heparin is a pork-derived product and one of the oldest drugs currently still in widespread clinical use, having been used since the early 1990s.
- 13. Heparin works by decreasing the clotting ability of the blood, thereby preventing the

actual formation of clots or preventing the extension of existing clots within the blood.

- 14. It is most often administered intravenously and is used primarily to decrease the chance of clots forming in patients undergoing certain medical procedures such as cardiac surgery, in preventing the formation of clots in catheters (small plastic tubes through which medication is administered or blood drawn) such as in kidney dialysis, and for other such conditions like pulmonary emboli.
- 15. The Food and Drug Administration ("FDA") estimates that more than 1 million multiple-dose vials are sold each month in the United States.
- 16. Baxter is one of the largest producers of Heparin in the United States, and its sales of heparin constitute at least a 50% market share.
- 17. Baxter sells an estimated 35 million units of Heparin per year, with annual sales of approximately \$30 million dollars.
- 18. Baxter reported total sales in the amount of \$11.3 billion dollars for 2007, with over 70% of its revenues being sourced form products in market-leading positions.
- 19. The multiple-dose heparin vials were represented by Defendants to be safe and effective for their intended uses, including, but not limited to, intravenous administration during hemodialysis.
- 20. The multiple-dose heparin vials were defective in their manufacture.
- 21. Defendants are designers, developers, manufacturers, wholesales, retailers, fabricators, suppliers and/or distributors of the multiple-dose heparin vials, one or more of which was administered to the Paul Hills during a hemodialysis session or sessions.
- 22. The multiple-dose heparin vials were manufactured, fabricated, distributed, supplied and/or placed in the stream of interstate commerce by Defendants.
- 23. Defendants obtained the component parts for the multiple-dose heparin vials from unidentified supply companies, including, but not limited to, Protein Scientific Laboratories, who has two plants which supply the active pharmaceutical ingredient for heparin to Defendants.
- 24. The active pharmaceutical ingredient in heparin is an enzyme that is extracted from pig intestines.
- 25. One of these plants is located in China and upon information belief, has not met the requisite requirements for importation and/or sale within the United States.
- 26. Such requirements include, but are not necessarily limited to, inspection and approval by the Food and Drug Administration as is required for any facility to supple drug ingredients to the

United States.

- 27. Upon information and belief, Defendants knew or should have known of such non-compliance or lack of plant inspection and/or approval, which is required for all foreign facilities.
- 28. Such multiple-dose heparin vials were defective at the time they were placed in the stream of commerce.
- 29. Baxter knew or should have known that these multiple-dose heparin vials were defective at the time they left Baxter's control and custody.
- 30. Defendants also knew or should have known that the multiple-dose heparin vials were causing adverse reactions for patients, such as Paul Hills.
- 31. Nothwithstanding their knowledge, Baxter continued to supply and sell the multiple-dose heparin vials up to and until just recently, without providing any warnings about the risks and drugs associated with the multiple-dose heparin vials to members of the public and the medical community, including Paul Hills.
- 32. At all material times, Baxter intentionally concealed from the public and members of the medical community, including Paul Hills, the risks and dangers associated with the use of the multiple-dose heparin vials, and/or has misrepresented the safety, quality and performance of multiple-dose heparin vials.
- 33. On or about January 17, 2008, Baxter and the FDA both issued press releases regarding the voluntary recall by Baxter of nine lots of Heparin Sodium Injection multiple dose vials in 1000 units/mL concentrations of 10mL and 30mL vials, 5000 units/mL concentration of 10mL vials and 10,000 units for 4mL vials.
- 34. This voluntary recall was the result of an abnormal increase in the reports of adverse patient reactions associated with the use of heparin.
- 35. These adverse patient reactions included the following: allergic or hypersensitivity-type reactions, with symptoms of oral swelling, abdominal pains, burning sensation, chest pain, diarrhea, dizziness, drug ineffectiveness, dyspepsia, dyspnea, erythema, flushing, headache, hyperhidrosis, hypoesthesia, increased lacrimation, loss of consciousness, malaise, nausea, pallor, palpitations, paresthesia, pharyngeal edema, restlessness, vomiting/retching, shortness of breath, stomach discomfort, sweating, tachycardia, thirst, trismus, and unresponsiveness to stimul, as well as cases of severe hypotension requiring treatment.
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- c. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2008, Lot #047056
- d. Heparin 1000 units/mL, 30 mL vial, expiration date 9/2009, Lot #097081
- e. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2009, Lot #107024
- f. Heparin 1000 units/mL, 30mL vial, expiration date 10/2009, Lot #107064
- g. Heparin 1000 units/mL, 30mL, expiration date 10/2009, Lot #107066
- h. Heparin 1000 units/mL, 30 mL, expiration date 10/2009, Lot #107074
- i. Heparin 1000 units/mL, 30 mL, expiration date 10/2009, Lot #107111
- 42. Upon information and belief, these nine lots were all manufactured at a single facility between September and November of 207.
- 43. Upon information and belief, the active pharmaceutical ingredient in these products was at least in part provided by a third party supplier from an unapproved facility in China.
- 44. However, according to FDA updates, more recent information indicates that comparable adverse events are continuing to be reported that are associated with the use of multiple-dose heparin vials of different manufacturing lots than those identified in the initial voluntary recall.
- 45. The FDA began inspections of Baxter's manufacturing plant in Cherry Hill, New Jersey and its processes on or about January 16, 2008.
- 46. The FDA and CDC are continuing with an investigation to discover the underlying cause of these anomalous adverse events.
- 47. As of February 11, 2008, Baxter ceased production of all of its multiple-dose vials of injectible heparin due to the potentially life threatening adverse and allergic reactions and

incidents of hypotension that are being reported.

48. As a direct and proximate result of Defendants' defective multiple-dose heparin vials, Plaintiff has been injured and incurred substantial damages, including, but not limited to medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, and other damages for which Defendants are liable.

Paul Hills

- 48. On or about July 24, 2007, Paul Hills had a surgical procedure performed for an abdominal aortic aneurysm at Evanston Hospital in Evanston, IL.
- 49. On or about July 24, 2007, the aforesaid procedure performed on Paul Hills was successful and he was expected at that point in time to have a complete and full recovery.
- 50. On or about July 24, 2007, Paul Hills was administered the aforesaid contaminated Heparin manufactured by Baxter.
- 51. Following the July 24, 2007 procedure, Paul Hills manifested signs and symptoms consistent with the administration of contaminated heparin including: dizziness, fainting, stomach pain and a fast heart rate.
- 52. On and after July 24, 2007, Paul Hills had an extensive hospitalization due to complications from the contaminated heparin.
- 53. On and prior to July 24, 2007, Baxter Healthcare manufactured and distributed the aforesaid contaminated Heparin product which was unreasonably dangerous for its intended use and was defective.
- 54. Scientific Protein Laboratories owed a duty to exercise reasonable care in the design, manufacture, testing, marketing, distributing, sale, and/or post-sale surveillance of these products, including the dose given to Paul Hills, so that it could be safely used for the purpose for which it was intended, or in a reasonable foreseeable manner.
- 55. This duty included the duty not to introduce a dangerous and unfit pharmaceutical drug, such as the multiple-dose heparin vials, into the stream of commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side effects, up to and including death.
- 56. In breach of their duty of care, Scientific Protein Laboratories was negligent in the manufacturer, testing, distribution, marketing, sale, and/or post-sale surveillance of the multiple-dose heparin vials, including as follows:
- a. Baxter failed to exercise reasonable care in the manufacture of their multiple-dose heparin vials;

- b. Baxter failed to exercise reasonable care in the inspection of their multiple-dose heparin vials;
- c. Baxter failed to exercise reasonable care in the packaging of their multiple-dose heparin vials;
- d. Baxter failed to provide any and adequate warnings about the risks and dangers associated with the use of their multiple-dose heparin vials, as alleged herein;
- e. Baxter failed to completely, accurately and in a timely fashion, disclose the adverse events reports associated with the use of its multiple-dose heparin vials;
- f. Baxter failed to recall, withdraw, and remove their multiple-dose heparin vials from the market once they knew or should have known of the risks and dangers associated with the use thereof;
- g. Baxter failed to promptly respond to data, reports, and publications describing problems associated with their multiple-dose heparin vials by conducting adequate analysis, testing, and surveillance;
- h. Baxter failed to implement pre-marketing and post-marketing measures to notify and warn Paul Hills, as well as his physicians, medical providers, and other members of the medical community, of the risks and dangers associated with the use of the said multiple-dose heparin vials, and to recall the defective multiple-dose heparin vials;
- i. Baxter failed to adequately and reasonably establish, maintain and comport with acceptable quality control mechanisms to prevent defective products from entering the marketplace or from using unsafe ingredients;
- j. Baxter failed to adequately and reasonably ensure quality controls were in the place and as such controls were adhered to obtaining the component parts for the multiple-dose heparin vials, including, but not limited to, the active pharmaceutical ingredient;
- k. Baxter failed to adequately and reasonably ensure compliance with all applicable laws, regulations, and administrative approval or licensing requirements;
- 1. Baxter failed to adequately monitor and/or take reasonable precautions to ensure that the active pharmaceutical ingredients in heparin were of suitable quality and safety; and
 - m. Baxter was otherwise negligent and careless.
- 57. Baxter knew or should have known that patients/consumers such as Paul Hills would foreseeably suffer injury as a result of their failure to exercise ordinary care as described above.
- 58. Baxter's multiple-dose heparin vials were expected to and did reach Paul Hills without

substantial change in the condition as designed, manufactured, marketed, distributed, and sold, prior to their administration to Paul Hills, who used the heparin as intended, or in a reasonably foreseeable manner.

- 59. Baxter's negligent conduct caused substantial harm to Paul Hills.
- 60. As a direct and proximate result of this defective product, Plaintiff has been injured and incurred substantial damages, including, but not limited to medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, and other damages for which Defendants are liable.

WHEREFORE, plaintiff, PAUL HILLS by his attorneys, POWER ROGERS & SMITH, demands judgment against Defendant, SCIENTIFIC PROTEIN LABORATORIES, in such sum of money in excess of FIFTY THOUSAND DOLLARS (\$50,000.00) as shall represent fair and just compensation.

Respectfully Submitted,

PAUL/HILLS

Course for Plaintiff

Devon C. Bruce POWER, ROGERS & SMITH 70 W. Madison Street, Suite 5500 Chicago, IL 60602 #312/236-9381 f#312/236-0920 * * * * D T C D T * * *

CASE 08-L-004473

HILLS PAUL

BAXTER HEALTHCARE CORP

THERE WILL BE A CASE MANAGEMENT CALL OF YOUR CASE ON TUESDAY THE 19TH DAY OF AUGUST IN ROOM 2208 AT 9:30 A.M. AT THE DALEY CENTER COURT HOUSE, 50 WEST WASHINGTON STREET, CHICAGO, IL

* * ATTENTION * * *

ALL ATTORNEYS OF RECORD MUST APPEAR

EXHIBIT B

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS COUNTY DEPARTMENT, LAW DIVISION

PAUL HILLS,)	
Plaintiff,)	
)	
v.)	No. 2008-L-004473
BAXTER HEALTHCARE CORP.,)	Judge Jeffrey Lawrence
BAXTER INTERNATIONAL, INC. and)	
WYETH SUBSIDIARY ILLINOIS)	
CORPORATION F/K/A SCIENTIFIC)	
PROTEIN LABORATORIES,)	
)	
Defendants.)	

DATH HILLS

NOTICE OF REMOVAL TO DISTRICT COURT

Defendants Baxter Healthcare Corporation and Baxter International Inc. ("Defendants") hereby give notice to the Circuit Court of Cook County, Illinois, and to Devon C. Bruce, as attorney for plaintiff, that the defendants filed a Notice of Removal with the United States District Court for the Northern District of Illinois, and that this case has been removed to that court. A true and correct copy of the Notice of Removal is attached as Exhibit A.

Dated this 10th day of June, 2008

Respectfully submitted,

Leslie M. Smith, P.C. Renee D. Smith Andrew P. Bautista Kirkland & Ellis LLP (No. 90443) 200 East Randolph Drive Chicago, IL 60601

telephone: (312)861-2000 facsimile: (312)861-2200

CERTIFICATE OF SERVICE

I, Leslie M. Smith, P.C., certify that on June 10, 2008, I caused a true and correct copy of Defendants NOTICE OF REMOVAL TO DISTRICT COURT to be served on plaintiff's counsel, by overnight delivery:

Devon C. Bruce POWER, ROGERS & SMITH 70 W. Madison Street, Suite 5500 Chicago, IL 60602

telephone: (312)236-9381 facsimile: (312)236-0920

Leslie M. Smith, P.C.	